NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSING

Editor's Note: The following Notice of Supplemental Proposed Rulemaking was reviewed per the Governor's Regulatory Review Plan memorandum, January 22, 2009 and its continuations on April 30, June 29, and October 16, 2009. (See a copy of the memoranda in this issue on pages 1861 through 1863.) The Governor's Office authorized the notice to proceed through the rulemaking process on March 13, 2009.

[R09-102]

PREAMBLE

1. The Register citation and dates for the Notice of Rulemaking Docket Opening, the Notice of Proposed Rulemaking, and any Notices of Supplemental Proposed Rulemaking, if applicable:

Notice of Rulemaking Docket Opening: 15 A.A.R. 300, January 30, 2009

Notice of Proposed Rulemaking: 15 A.A.R. 590, April 10, 2009

Notice of Proposed Rulemaking: 15 A.A.R. 786, May 15, 2009 - Correction to 15 A.A.R. 590, April 10, 2009

Notice of Public Information: 15 A.A.R. 798, May 15, 2009

Notice of Rulemaking Docket Opening: 15 A.A.R. 1858, November 6, 2009 (in this issue)

2. Sections Affected Rulemaking Action

R9-10-115	Amend
R9-10-203	Amend
R9-10-1501	Amend
R9-10-1503	Amend
R9-10-1505	Amend
R9-10-1506	Amend
R9-10-1507	Amend
R9-10-1508	Amend
R9-10-1511	Amend
R9-10-1702	Amend

3. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-104(3), 36-132(A)(3), and 36-136 Implementing statutes: A.R.S. §§ 36-405, 36-406, and 36-449.03

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Thomas Salow, Acting Manager of Administrative Counsel and Rules

Address: Department of Health Services 1740 W. Adams St., Suite 200

Phoenix, AZ 85007

Telephone: (602) 542-1264
Fax: (602) 364-1150
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or

Notices of Supplemental Proposed Rulemaking

Name: Kathy McCanna, Program Manager

Address: Department of Health Services

Division of Licensing Services Office of Medical Facilities Licensing

150 N. 18th Ave. Phoenix, AZ 85007

Telephone: (602) 364-2841 Fax: (602) 364-4764

E-mail: mccannk@azdhs.gov

5. An explanation of the rule, including the agency's reasons for initiating the rules:

A.R.S. § 36-405(A) requires the Department of Health Services (Department) to adopt rules establishing minimum standards and requirements for the construction, modification and licensure of health care institutions necessary to assure the public health, safety and welfare. It further requires that the standards and requirements relate to the construction, equipment, sanitation, staffing for medical, nursing, and personal care services, and recordkeeping pertaining to the administration of medical, nursing, and personal care services according to generally accepted practices of health care. A.R.S. § 36-405(B) allows the Department to class and subclass health care institutions according to character, size, range of services provided, medical or dental specialty offered, duration of care and standard of patient care required. Laws 1999, Ch. 311, § 2 defined and added abortion clinics as a health care institution class.

A.R.S. §§ 36-449 and 36-449.01 through 36-449.03, effective August 6, 1999, establish the requirements for abortion clinics. A.R.S. § 36-449.01 defines "abortion clinic" as a "facility, other than an accredited hospital, in which five or more first trimester abortions in any month or any second or third trimester abortions are performed." A.R.S. § 36-449.03 directs the Department to adopt rules regarding an abortion clinic's physical facilities, personnel, medical screening and evaluation of patients, abortion procedures, incident reporting, and standards for supplies, equipment, recovery rooms, and follow-up visits.

A.A.C. Title 9, Chapter 10, Article 15, provides the minimum standards and requirements for abortion clinics in Arizona. The rules address an abortion clinic's application requirements, administration, incident reporting, personnel qualifications and records, staffing requirements, patient rights, abortion procedures, patient transfer and discharge, medications and controlled substances, medical records, environmental and safety standards, equipment standards, and physical facilities. The rules were adopted by exempt rulemaking, effective April 1, 2000, and amended by exempt rulemaking, effective January 1, 2001.

On March 1, 2000, the Center for Reproductive Rights filed a federal challenge to the abortion clinic rules on behalf of several abortion providers, including Tucson Woman's Clinic, seeking to block implementation. After the suit was filed, the Department agreed not to enforce the rules during the District Court proceedings and subsequent appeals. Accordingly, the abortion clinic rules have not been implemented.

In *Tucson Woman's Clinic* v. *Eden*, No. CV-00-00141-RCC (D. Ariz. Sept. 30, 2002), the District Court in substantial part upheld the abortion clinic rules but struck down rule provisions that provided state officials with unannounced access to abortion clinics during business hours and allowed state officials to review unredacted patient records and ultrasound prints. The District Court's decision was appealed to the U.S. Court of Appeals for the Ninth Circuit and the decision was affirmed in part, reversed in part, and remanded to the District Court for further proceedings. *Tucson Woman's Clinic* v. *Eden*, No. 02-17375, No. 02-17382, 2004 U.S. App. LEXIS 12015 (9th Cir. June 18, 2004). Among other things, the Court of Appeals:

- Agreed with the District Court that the statutory and regulatory scheme authorized boundless, warrantless searches of abortion clinics and violated the abortion patients' Fourth Amendment rights;
- Held that allowing access to unredacted abortion medical records and sending ultrasound prints to a private contractor violated abortion patients' right to privacy;
- Agreed with the District Court that some provisions were not clear enough to let physicians know when they
 have violated the rule and were unconstitutionally vague; and
- Disagreed with the District Court's decision that the law did not impose an undue burden on the plaintiffs and ruled that this was an issue of material fact, remanding the matter for trial.

On September 10, 2008, the Department and the other defendants and the plaintiffs filed a Stipulation of Settlement and a Joint Request for an Order Approving and Mandating Compliance with Stipulation of Settlement that was approved by the District Court. Within 120 calendar days of the District Court's approval, the Department agreed to begin the rulemaking process to amend the abortion clinic rules according to Exhibit A of the Stipulation. A Notice of Rulemaking Docket Opening for 9 A.A.C. 10, Article 15, Abortion Clinics, was filed on January 6, 2009. In the Stipulation, the Department also agreed to follow all requirements in the rulemaking process requirements in proposing and supporting the rule revisions in the Stipulation. This rulemaking contains the amendments that the Department agreed to propose and support as part of the Stipulation including:

• Adding definitions for "admission," "admitting privileges," and "personally identifiable patient information";

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- Deleting provisions requiring the Department's immediate access to the abortion clinic and adding provisions for the Department's access to the abortion clinic by appointment or with an administrative search warrant;
- Amending provisions for training requirements for individuals performing ultrasounds;
- Deleting requirements for a patient care staff and volunteer written work schedule;
- Deleting the requirement for a patient to be treated with consideration, respect, and full recognition of the
 patient's dignity and individuality, which the Court of Appeals found to be unconstitutionally vague;
- Amending the requirement for establishing an intravenous access on a patient undergoing an abortion after the first trimester;
- Deleting the requirement for submitting an ultrasound to a person or corporation contracted with the Department in compliance with A.R.S. § 36-2301.02;
- Amending the requirements for scheduling a follow-up visit following an abortion; and
- Amending the requirements for providing abortion patient medical records for the Department's review.

Currently there are licensed health care institutions regulated by the Department that provide abortions. These health care institutions are currently required to comply with the rules in 9 A.A.C. 10 for the health care institution's applicable class or subclass. When the abortion clinic rules are implemented, health care institutions that meet the definition of "abortion clinic" in A.R.S. § 36-449.01 will be required to meet the requirements in the abortion clinic rules when providing abortions. If the health care institution provides medical services, nursing services, or health-related services other than those services related to abortions, the health care institution can select any of the following three licensing options: 1) continue to comply with the rules in 9 A.A.C. 10 that are applicable to the health care institution's current class or subclass and comply with the rules in 9 A.A.C. 10, Article 15, when providing abortions; 2) comply only with the rules in 9 A.A.C. 10, Article 15, and limit the services the health care institution provides to those abortion services regulated under A.R.S. § 36-449.01(1); or 3) delineate a portion of the currently licensed premises that will provide abortions and related services in compliance with 9 A.A.C. 10, Article 15 and delineate a separate portion of the currently licensed premises that will not provide abortions or related services but will continue to comply with the specific rules in 9 A.A.C. 10 for the health care institution's class or subclass.

6. An explanation of the substantial change which resulted in this supplemental notice:

Based on written and oral comments, the Department made the following changes to the proposed rules:

Preamble

In item 5 of the Preamble of the Notice of Proposed Rulemaking, it was stated that the only way for a facility to comply with the abortion rules and any other applicable health care institution rules was to have premises and records for the abortion clinic separate from the premises and records for the licensed health care institution. The Department has deleted the references to separate premises and separate records, and instead has provided three options for currently licensed health care institutions that meet the definition of "abortion clinic" in A.R.S. § 36-449.01.

R9-10-115

The Department amended the rule by deleting outdated references and language, restructuring subsections for clarity, and adding a subsection requiring a health care institution that meets the definition of "abortion clinic" in A.R.S. § 36-449.01, to comply with the requirements in 9 A.A.C. 10, Article 15 when providing abortions and related services.

R9-10-203(E)

The Department added a subsection requiring a hospital that meets the definition of "abortion clinic" in A.R.S. § 36-449.01, to comply with the requirements in 9 A.A.C. 10, Article 15 when providing abortions and related services.

R9-1501(4)

In the definition of "admitting privileges" the Department deleted the phrase "within 30 miles of the abortion clinic" and added the phrase "in this state" consistent with statutory language.

R9-10-1501(21)

The Department deleted the definition of "hospital" and renumbered the remaining definitions accordingly.

R9-10-1501(40)

The Department restructured the definition of "personally identifiable patient information" using labeled subsections and added the term "carrier" to provide more clarity.

R9-10-1506(B)

The Department deleted the phrase "If a physician is not present in the facility" and added the phrases "A physician" and "or, if a physician is able to provide direct supervision as defined in A.R.S. § 32-1401, a medical assistant under the direct supervision of the physician" to the list of individuals allowed to monitor a patient in a recovery room.

R9-10-1702(B)(10)

Notices of Supplemental Proposed Rulemaking

The Department relabeled incorrectly labeled subsections and added a subsection requiring an outpatient surgical center that meets the definition of "abortion clinic" in A.R.S. § 36-449.01, to comply with the requirements in 9 A.A.C. 10, Article 15 when providing abortions and related services.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

Annual costs/revenue changes are designated as minimal when less than \$10,000, moderate when between \$10,000 and \$50,000, substantial when greater than \$50,000, and significant when meaningful or important but not readily subject to quantification.

Description of Affected Groups	Description of Effect	Increased Cost/ Decreased Revenue	Decreased Cost/ Increased Revenue	
A. State and Local Government Agencies				
Department	Limiting access to the abortion clinic and medical records by requiring an: - appointment for a licensing or compliance inspection, and - administrative search warrant for a complaint investigation	Minimal-to-moderate	None	
	Removing the requirement to submit ultrasound to a person contracted by the Department	None	Substantial	
B. Privately Owned Business				
Abortion clinics (non-accredited hospitals, outpatient treatment centers (OTCs), outpatient surgical centers (OSCs), and physicians in private practice licensed as abortion clinics)	Limiting access to the abortion clinic and medical records by requiring an: - appointment for a licensing or compliance inspection, and - administrative search warrant for a complaint investigation	Minimal-to-moderate	Significant	
	Removing requirement to maintain sched- ules of staff assigned to provide services and actually providing services	None	Minimal/significant	
	Clarifying that intravenous (IV) access is not required if a physician determines that IV access is not appropriate for the patient	Minimal	Minimal	
	Clarifying that an ultrasound may be maintained in a patient's medical record in either electronic or paper form	None	Minimal-to-moderate	
	Removing requirement to submit ultrasound to a person contracted by the Department	None	Minimal-to-moderate	
Physicians and other staff of an abortion clinic	Revising requirements to perform an ultrasound	None	Minimal	
	Removing requirement to maintain schedules of staff assigned to provide services and actually providing services	None	Significant	
C. Consumers		T	1	
Women seeking abortion services	Limiting access to the abortion clinic and medical records by requiring an: - appointment for a licensing or compliance inspection - administrative search warrant for a complaint investigation	Minimal	Significant	
	Clarifying that intravenous (IV) access is not required if a physician determines that IV access is not appropriate for the patient	None	Minimal/significant	
	Removing requirement to submit ultrasound to a person contracted by the Department	None	Significant	

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Thomas Salow, Acting Manager of Administrative Counsel and Rules

Address: Department of Health Services 1740 W. Adams St., Suite 200

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Phoenix, AZ 85007

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or

Name: Kathy McCanna, Program Manager

Address: Department of Health Services

Division of Licensing Services Office of Medical Facilities Licensing

150 N. 18th Ave. Phoenix, AZ 85007

Telephone: (602) 364-2841
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E-mail: mccannk@azdhs.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Date: December 7, 2009

Time: 1:30 p.m.

Location: 1740 W. Adams St., Conf. room 411

Phoenix, AZ 85007

Close of record: December 7, 2009 at 5:00 p.m.

A person may submit written comments on the proposed rules or the preliminary summary of the economic, small business, and consumer impact no later than 5:00 p.m. on December 7, 2009, to the individuals listed in items 4 and 9. Persons with a disability may request reasonable accommodations by contacting Valerie Grina at grinav@azdhs.gov or (602) 364-2580. Requests should be made as early as possible to allow sufficient time to arrange for the accommodation.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 1. GENERAL

Section

R9-10-115. Unclassified Health Care Institutions

ARTICLE 2. HOSPITALS

Section

R9-10-203. Administration

ARTICLE 15. ABORTION CLINICS

Section

R9-10-1501. Definitions R9-10-1503. Administration

R9-10-1505. Personnel Qualifications and Records

R9-10-1506. Staffing Requirements

Notices of Supplemental Proposed Rulemaking

R9-10-1507. Patient Rights R9-10-1508. Abortion Procedures R9-10-1511. Medical Records

ARTICLE 17. OUTPATIENT SURGICAL CENTERS

Section

R9-10-1702. Administration

ARTICLE 1. GENERAL

R9-10-115. Unclassified Health Care Institutions

Implementation of the provisions of R9-10-114(B) shall be at the sole discretion of the Director's representative. Health care institutions An administrator for a health care institution not otherwise classified or subclassified in R9-10-114(A) A.R.S. Title 36, Chapter 4, 9 A.A.C. 10, or 9 A.A.C. 20 shall include but need not be limited to the following:

- 1. Be adequately equipped and staff Adequately equip and staff the health care institution by with qualified personnel to meet the needs and assure ensure the health and safety of persons attending the facility patients and comply with applicable statutory requirements laws and rules for the provision of health care medical services, nursing services or health-related services.
- 2. Establish and maintain a record of each inpatient and outpatient documenting the assessment of the patient's health needs and all the health care services the medical services, nursing services, and health-related services the patient receives:
- 3. Maintain all parts of the facility <u>premises</u>, including its <u>premises and the facility's</u> equipment, neat, clean, free of insects, rodents, litter and rubbish:
- 4. Establish, document, and implement Policies policies and procedures shall be established and implemented for cleaning, sanitizing or sterilizing, and storing equipment and supplies:
- 4.5. Cause Ensure that the facility's physical plant and equipment to be are periodically inspected and, where appropriate, tested, calibrated, serviced or repaired to assure so that they the facility's physical plant and equipment are functioning properly and reliably:
- 6. Records shall be maintained Maintain physical plant and equipment inspection and maintenance records to assure that appropriate inspections and maintenance of equipment is accomplished by an appropriately a qualified person:
- 5.7. Comply with applicable regulations requirements adopted pursuant to A.R.S. § 36-136(G) for the control of communicable disease and maintenance of proper sanitation:
- 6.8. Comply with applicable fire and building codes:
- 7.9. Adopt Establish, document, and implement policies and procedures that delineate the scope of services offered, hours of operation, admission and discharge criteria and type of staff personnel provided.; and
- 8. Obtain certificates of need and/or permits, if applicable.
- 10. If the health care institution meets the definition of "abortion clinic" in A.R.S. § 36-449.01, ensure that abortions and related services are provided in compliance with the requirements in 9 A.A.C. 10, Article 15.

ARTICLE 2. HOSPITALS

R9-10-203. Administration

- **A.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
 - 9. No change
 - 10. No change
 - 11. No change
 - 12. No change
 - 13. No change
- B. No change
 - 1. No change
 - 2. No change

- 3. No change
- 4. No change
- C. No change
 - 1. No change
 - a. No change
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 - 6. No change
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 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
- **D.** No change
 - 1. No change
 - 2. No change
- E. An administrator of a hospital that meets the definition of "abortion clinic" in A.R.S. § 36-449.01, shall require that abortions and related services are provided in compliance with the requirements in 9 A.A.C. 10, Article 15.

ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions

In this Article, unless the context otherwise requires:

- 1. No change
- 2. No change
- "Admission" means documented acceptance by a hospital of an individual as an inpatient as defined in R9-10-201 on the order of a physician.
- 4. "Admitting privileges" means permission extended by a hospital to a physician to allow admission of a patient:
 - a. By the patient's own physician, or
 - Through a written agreement between the patient's physician and another physician that states that the other physician has permission to personally admit the patient to a hospital in this state and agrees to do so.
- 3-5. "Adverse reaction" means an unexpected occurrence that threatens the health and safety of a patient.
- 4.6. No change
- 5.7. No change
- 6.8. No change
- 7.<u>9.</u> No change
- 8.10. No change
- 9.11. No change
- 10.12. No change
- 11.13. No change
- 12.14. No change
- 13.15. No change
- 14.16. No change
- 15.17. No change
- 16.18. No change
- 17.19. No change
- 18.20. No change
- 19.21. No change
- 20.22. No change
- 21.23. No change
- 22.24. No change
- 23.25. No change
- 24.26. No change
- 25.27. No change 26.28. No change
- 27.29. No change
- 28.30. No change
- 29.31. No change
- 30.32. No change
- 31.33. No change
- 32.34. No change
- 33.35. No change
- 34.36. No change
- 35.37. No change
- 36.38. No change
- 39. "Personally identifiable patient information" means:
 - The name, address, telephone number, e-mail address, Social Security number, and birth date of:
 - <u>i.</u> The patient,
 - ii. The patient's representative,
 - iii. The patient's emergency contact,
 - iv. The patient's children,
 - The patient's spouse,
 - v. The patient's spouse,vi. The patient's sexual partner, and
 - vii. Any other individual identified in the patient's medical record other than patient care staff;
 - b. The patient's place of employment;
 - c. The patient's referring physician;
 - d. The patient's insurance carrier or account; and
 - e. Any other information in the patient's medical record that could reasonably lead to the identification of the patient.

37.40. No change

- 38.41. No change
- 39.42. No change
- 40.43. No change
- 41.44. No change
- 42.45. No change
- 43.46. No change
- 44.47. No change
- 45.48. No change

R9-10-1503. Administration

- A. No change
- **B.** A licensee shall:
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. Ensure that the Department's director or director's designee is allowed immediate access to the abortion clinic during the hours of operation; as follows:
 - a. For a complaint inspection, upon presentation of an administrative search warrant authorizing the inspection of the abortion clinic; or
 - b. For a licensing or compliance inspection, at a date and time agreed to by the licensee and the Department that is no later than 10 business days after the date the Department submits a written request to the licensee to schedule the licensing or compliance inspection, unless the Department agrees to a later date and time;
 - 5. No change
 - a. No change
 - b. No change
 - c. No change
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 7. No change8. No change
 - 9. No change

R9-10-1505. Personnel Qualifications and Records

A licensee shall ensure that:

- 1. No change
 - a. No change
 - b. No change
- 2. No change
- 3. No change
 - a. A physician who:
 - Has completed a course in performing an ultrasound from a manufacturer or distributor of ultrasound equipment; or
 - ii. Has performed ultrasounds during the physician's medical education;
 - b. A physician assistant, nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician qualified as required in subsection (3)(a); or
 - c. An individual who completed:
 - i. A postsecondary education institution course in performing ultrasound; Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
 - ii. The hands-on course required in subsection (3)(b) Is not otherwise precluded by law from performing an ultrasound.
- 4. No change
- 5. No change

- a. No change
- b. No change
- c. No change
- d. No change
- e. No change
- f. No change
- 6. No change

R9-10-1506. Staffing Requirements

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
- B. No change
 - 1. No change
 - 2. A physician with admitting privileges at an accredited hospital in this state is in the physical facilities remains on the premises of the abortion clinic until each patient is all patients are stable and ready to leave the recovery room; and
 - 3. A physician, a nurse, a nurse practitioner, or a physician assistant, or, if a physician is able to provide direct supervision as defined in A.R.S. § 32-1401, a medical assistant under the direct supervision of the physician:
 - a. No change
 - b. Remains in the physical facilities facility until each patient is discharged by a physician; and
 - 4. A written schedule is maintained in the physical facilities for at least six months from the last date on the schedule and includes:
 - a. The date, work hours, and name of the patient care staff assigned to provide medical services, nursing services, health related services, and the name of the volunteers assigned to provide volunteer services; and
 - b. The date, work hours and name of the patient care staff and volunteers who actually provided medical services, nursing services, health-related services, or volunteer services.

R9-10-1507. Patient Rights

A licensee shall ensure that a patient is afforded the following rights, and is informed of these rights:

- 1. To be treated with consideration, respect, and full recognition of the patient's dignity and individuality;
- 2.1. To refuse treatment, or withdraw consent for treatment;
- 3.2. No change
- 4.3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

R9-10-1508. Abortion Procedures

- **A.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - 2. No change
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- **B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- 5. No change
- C. No change
 1. No change
 - 2. No change

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- **D.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - a. No change
 - b. Maintained in the patient's medical record in either electronic or paper form; and
 - 4. No change
- E. No change
 - 1. No change
 - 2. No change
- F. No change
- G. No change
 - 1. No change
 - 2. Intravenous access is established and maintained on a patient undergoing an abortion after the first trimester <u>unless</u> the physician determines that establishing intravenous access is not appropriate for the particular patient and documents that fact in the patient's medical record; and
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
- H. No change
 - 1. A patient's vital signs and bleeding are monitored by a member of the patient care staff, except a surgical assistant, to ensure the patient's health and recovery; and
 - 2. A patient remains in the recovery room or recovery area until a physician, physician assistant, a nurse practitioner or a nurse examines the patient and determines that the patient's medical condition is stable and the patient is ready to leave the recovery room or recovery area; and.
 - 3. An ultrasound result print of each fetus with a gestational age estimate of more than 12 weeks is sent to persons or corporations contracted with the Department in compliance with A.R.S. § 36-2301.02.
- I. No change
 - 1. No change
 - 2. A follow-up visit offered <u>and scheduled, if requested, at least three weeks no more than 21 days</u> after the abortion, which includes. The follow-up visit shall include:
 - a. A physical examination;
 - b. A review of all laboratory tests as required in R9-10-1508(A)(3); and
 - c. A urine pregnancy test.
- J. No change

R9-10-1511. Medical Records

- **A.** No change
 - 1. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
 - 2. No change
 - 3. No change
 - 4. No change a.5. No change
 - b. A medical record maintained at the abortion clinic is provided to the Department for review no later than two hours from the time the Department requests the medical record; and
 - e. A medical record maintained off-site is provided to the Department for review no later than 24 hours from the time the Department requests the medical record;

Notices of Supplemental Proposed Rulemaking

- 5.6. No change
- 6.7. No change
- **B.** A licensee shall comply with Department requests for access to or copies of patient medical records as follows:
 - 1. For patient medical records requested for review in connection with a compliance inspection, the licensee shall provide the Department with the following patient medical records related to medical services associated with an abortion, including any follow-up visits to the facility in connection with the abortion:
 - a. Name and address of patient and patient's representative;
 - b. Written acknowledgement of the receipt of patient rights;
 - c. Documentation of advanced directives;
 - d. Admitting diagnosis;
 - e. Medical history and physical examination reports:
 - f. Laboratory and radiology reports, if any;
 - g. Consent forms:
 - h. Physician orders and notations;
 - i. Surgeon's operative report;
 - <u>i.</u> Anesthesia report;
 - k. Nursing care notations;
 - 1. Medications and treatments administered; and
 - m. Written acknowledgement of receipt of discharge instructions by the patient or patient's representative.
 - 2. For patient medical records requested for review in connection with an initial licensing or compliance inspection, the licensee is not required to produce for review by the Department any patient medical records created or prepared by a referring physician or any of that referring physician's medical staff.
 - 3. The licensee is not required to provide patient medical records regarding medical services associated with an abortion, including any follow-up visits to the facility in connection with an abortion, that occurred before the effective date of these rules or before a previous licensing or compliance inspection of the licensee by the Department.
 - 4. The patient medical records may be provided to the Department in either paper or in an electronic format that is acceptable to the Department.
 - 5. When access to or copies of patient medical records are requested from a licensee by the Department, the licensee shall redact only personally identifiable patient information from the patient medical records before the disclosure of the patient medical records to the Department, except as provided in (B)(8).
 - 6. For patient medical records requested for review in connection with an initial licensing or compliance inspection, the licensee shall provide the redacted copies of the patient medical records to the Department within two business days of the Department's request for the redacted medical records if the total number of patients for whom patient medical records are requested by the Department is from one to 10 patients, unless otherwise agreed to by the Department and the licensee. The time within which the licensee shall produce redacted records to the Department shall be increased by two business days for each additional five patients for whom patient medical records are requested by the Department, unless otherwise agreed to by the Department and the licensee.
 - 7. Upon request by the Department, in addition to redacting only personally identifiable patient information, the licensee shall code the requested patient medical records by a means that allows the Department to track all patient medical records related to a specific patient without the personally identifiable patient information.
 - 8. The Department shall have access to or copies of unredacted patient medical records only pursuant to an administrative search warrant specifically authorizing the disclosure of unredacted patient medical records by the licensee.
 - 9. If the Department obtains copies of unredacted patient medical records, the Department shall:
 - a. Allow the examination and use of the unredacted patient medical records only by those Department employees who need access to the patient medical records to fulfill their investigative responsibilities and duties;
 - b. Maintain all unredacted patient medical records in a locked drawer, cabinet, or file or in a password-protected electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records pursuant to (B)(9)(a);
 - c. Destroy all unredacted patient medical records at the termination of the Department's investigation or at the termination of any administrative or legal action that is taken by the Department as the result of the Department's investigation, whichever is later;
 - d. File the unredacted patient medical records with a court or other judicial body, including any administrative law judge or panel, only under seal; and
 - e. Prevent access to the unredacted records by anyone except as provided in subsection (B)(9)(a) or subsection (B)(9)(d).

B.C. No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change

- c. No change
- d. No change
- 3. No change
- 4. No change
- 5. No change
 - a. No change
 - b. No change
 - c. No change
- 6. No change

C.D. No change

ARTICLE 17. OUTPATIENT SURGICAL CENTERS

R9-10-1702. Administration

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- B. No change
 - a.1. No change
 - b.2. No change
 - e.3. No change
 - i.a. No change
 - ii.b. No change
 - iii.c. No change
 - iv.d. No change
 - v.e. No change
 - vi.f. No change
 - vii.g. No change
 - viii.h. No change
 - ix.i. No change
 - 11. 1 10 Chan
 - d.4. No change
 - e.5. No change f.6. No change
 - g.7. No change
 - h.8. Ensure that pathology services are provided by a laboratory licensed, or exempt from licensure, pursuant to A.R.S. Title 36, Chapter 4.1; and
 - i.9. Designate, in writing, an individual to be on duty, in charge, and have access to all areas related to patient care and operation of the physical plant when the administrator is not present.: and
 - 10. If the outpatient surgical center meets the definition of "abortion clinic" in A.R.S. § 36-449.01, ensure that abortions and related services are provided in compliance with the requirements in 9 A.A.C. 10, Article 15.